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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#15

In re the Application for Extension of Patent Term of

U.S. Patent No.: Re. 32,969

Reissued Date of Patent: June 27, 1989

Reissue of: U.S. Patent No. 4,540,568

Issued: September 10, 1985

Patentee: Trager et al.

Title: INJECTIONABLE VISCOELASTIC OPHTHALMIC GEL

APPLICATION FOR EXTENSION OF PATENT TERM

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

Sir:

Pursuant to 35 USC 156, the patent owner respectfully requests extension of patent term for the above-captioned patent. Applicant respectfully submits that the conditions for extension of patent term under 37 CFR 1.720 are met. The items required by 37 CFR 1.740(a) follow in §§ I-XVII.

I. Approved Product

The approved product is an injectionable viscoelastic ophthalmic gel having the tradename "ORCOLON". The generic chemical name is polyacrylamide. The product formulation contains 45 mg/ml of polyacrylamide dissolved in a balanced salt solution.

The approved product is sterile, transparent, viscoelastic, nonpyrogenic and nonionic, and has a pH of 7.2 $\pm$ 0.3. The

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polyacrylamide is a synthetic homopolymer of acrylamide, made of long chains of carbon atoms commonly found in fatty acids, carotenoids and natural rubber, and has a molecular weight of about one million. The viscosity of the approved product is 40,000 ± 10,000 centipoise and the osmolarity of the approved product is 340 + 40 or -25 milliosmoles.

Each milliliter of the approved product consists of 4.5 wt.% purified polyacrylamide having a weight average molecular weight of about 1 million, 0.39 wt.% sodium chloride, 0.06 wt.% potassium chloride, 0.04 wt.% calcium chloride dihydrate, 0.02 wt.% magnesium chloride hexahydrate, 0.17 wt.% sodium citrate dihydrate, 0.39 wt.% sodium acetate trihydrate and remainder sterile water.

The approved product is supplied in sterile, disposable glass syringes delivering 0.75 ml of the approved product. The product is indicated for use as a surgical aid in anterior segment procedures including cataract extractions and intraocular lens (IOL) implantation. The approved product acts as an ocular space-occupying fluid during surgery and is gradually replaced by the body's natural fluids.

In cataract extraction surgery, the approved product aids in maintaining a deep anterior chamber. In IOL implantation, the approved product aids in protecting the corneal endothelium and other ocular structures by effectively coating the IOL, surrounding tissues and surgical instruments.

II. Applicable Federal Statute

Regulatory review for premarket approval (PMA) of the "ORCOLON" medical device occurred under authority of § 515 of the Federal Food, Drug, and Cosmetic Act ("Act"). June 25, 1938, c. 675, § 515 as added May 28, 1976, Pub.L. 94-295, § 2, 90 Stat. 552, amended Nov. 28, 1990, Pub.L. 101-629, §§ 4(b)(1), 9(a), 18(c), 104 Stat. 4515, 4521, 4528.

III. Product Approval Date

The "ORCOLON" medical device received premarket approval under the authority of § 515 of the Act on March 29, 1991.

IV. Identification of Drug Product Ingredients

The approved product is a "medical device", not a "drug product" as defined in 35 USC 156(f)(2). Accordingly, 37 CFR 1.740(a)(4) is inapplicable.

V. Application Filing Deadline

The present application is being submitted within the sixty-day period permitted for submission pursuant to 37 CFR 1.720(f). The last day on which the application can be submitted is May 28, 1991.

VI. Patent For Which Extension Is Sought

The patent for which an extension is being sought is U.S. Patent No. Re. 32,969, issued June 27, 1989, to Seymour F. Trager and Victoria S. Chylinski, which expires September 10, 2002.

VII. Copy Of Patent

A copy of Re. 32,969 is attached hereto, including the entire specification and claims.

VIII. Copy of Certificate of Correction

A copy of the Certificate of Correction for Re. 32, 969, dated April 24, 1990, is also included with the enclosed copy of the reissue patent.

There are no disclaimers, maintenance fee payment receipts (the original patent having been surrendered with the filing of the reissue application prior to the due date for the first maintenance fee), or reexamination certificates of record in Re. 32,969.

IX. Showing That Patent Claims Approved Product

Reissue patent Re. 32,969 claims the approved "ORCOLON" product or a method of using said product.

The following patent claims read directly on the approved product:

Product Claims

Claim 1 reads on the approved product. The preamble of claim 1 recites "[a]n injectionable viscoelastic gel particularly adapted for use in ophthalmic surgical procedures and treatments". As explained in § I above, the approved product is a viscoelastic gel indicated for use as an injectable surgical aid in anterior segment procedures including cataract extractions and intraocular lens (IOL) implantation, acting as an ocular space-occupying fluid during surgery.

The positive limitations recited in the body of claim 1 are met by the approved product. According to claim 1, "said gel consists essentially of from about 2 to about 5 percent by weight of a polymer selected from polyacrylamide and polymethacrylamide, said polymer having a molecular weight of from about 1 to about 6 million". The approved product consists essentially of 4.5 wt.% polyacrylamide polymer having a molecular weight of about 1 million, thus meeting the claim 1 limitation with respect to this ingredient.

According to claim 1, the gel further consists essentially of:

"from about 0.4 to about 8.6 percent by weight sodium chloride," which is met by the 0.39 wt.% sodium chloride content of the approved product, since 0.39 is 0.4 to one significant digit and about 0.4;

"from about 0.075 to about 0.3 percent by weight potassium chloride," which is met by the 0.06 wt.%

potassium chloride in the approved product since 0.06 is about 0.075;

"from about 0.04 to about 0.33 percent by weight calcium chloride," which is met by the 0.04 wt.% calcium chloride dihydrate (i.e., 0.03 wt.% anhydrous calcium chloride) in the approved product since 0.03 is about 0.04;

"from about 0.02 to about 0.04 percent by weight magnesium chloride hexahydrate," which is met by the 0.02 wt.% magnesium hexahydrate contained in the approved product;

"from about 0.3 to about 0.4 percent by weight sodium acetate, which is met by the 0.39 wt.% sodium acetate trihydrate (i.e., 0.24 wt.% anhydrous sodium acetate) in the approved product since 0.24 is about 0.3;

"from about 0.15 to about 0.20 percent by weight of a buffer," which is met by the 0.17 wt.% sodium citrate dihydrate of the approved product, since sodium citrate dihydrate is disclosed in the patent as being a suitable buffer (see claim 5); and

"remainder water", which is met by the approved product as explained in § I above.

In addition to claim 1, independent claims 2, 3 and 5 read on the approved product. Claim 2 recites "[a] gel as defined in claim 1 wherein said polymer is polyacrylamide." The polymer ingredient

of the approved product is polyacrylamide. Product claim 3 recites "[a] gel as defined in claim 1 wherein said polymer is present in an amount of from about 3.5 to about 4.5 percent by weight." The polyacrylamide of the approved product is present in an amount of 4.5 wt.%. Claim 5 requires "[a] gel as defined in claim 1 wherein said buffer is sodium citrate dihydrate." Since the approved product contains 0.17 wt.% sodium citrate dihydrate, claim 5 reads on the claimed product.

Thus, product claims 1-3 and 5 of Re. 32,969 directly read on the approved product.

Method Claims

Method claims 7-14 read on a method of using the approved product. Independent claim 7 recites a method of using a "viscoelastic gel comprising a polymer selected from polyacrylamide..., said polymer having a molecular weight of from about 1 to 6 million, and a pharmaceutically acceptable diluent therefor." The approved product, as explained above, contains a polyacrylamide polymer having a molecular weight of about 1 million and a pharmaceutically acceptable diluent in the form of a balanced salt solution. Thus, claim 7 reads directly on a method of using the approved product.

Specifically, claim 7 recites "[a] method for protecting ocular tissue during ophthalmic surgery which comprises injecting into an ocular chamber prior to said surgery an amount of viscoelastic gel sufficient to prevent mechanical damage and

denudation of said ocular tissue during said surgery". Claim 8 limits the surgical procedure to "an anterior segment surgical procedure". Claim 9 further limits the surgical procedure to "cataract removal, corneal transplant, keratoplasty or bullous rhegmatogenous retinal detachment". As described in § I above, the approved product is indicated for use as a surgical aid in anterior segment procedures including cataract extractions and intraocular lens (IOL) implantation. The approved product acts as an ocular space-occupying fluid during surgery and is gradually replaced by the body's natural fluids. In cataract extraction surgery, the approved product aids in maintaining a deep anterior chamber. In IOL implantation, the approved product aids in protecting the corneal endothelium and other ocular structures by effectively coating the IOL, surrounding tissues and surgical instruments. Accordingly, method claims 7-9 directly read on the indicated use of the approved product.

Dependent claims 10-14, further limiting the viscoelastic gel recited in claim 7, also read on a method of using the approved product. Claims 10-13 respectively recite that the polymer is present in an amount: "between about 2 to about 5 percent by weight of said viscoelastic gel" (claim 10); "between about 3.5 to about 4.5 percent by weight of said viscoelastic gel" (claim 11); "between about 4.5 to about 5.5 percent by weight of said viscoelastic gel" (claim 12); and, "in an amount between [*sic*: of] about 4 percent by weight of said viscoelastic gel" (claim 13).

The polymer of the approved viscoelastic gel product is present in an amount of 4.5% by weight of the gel, which is within the ranges recited in claims 10-12. Moreover, 4.5% by weight is about 4% by weight (to one significant figure) as recited in claim 13. Thus, claims 10-13 read on a method of using the approved product.

Claim 14 recites the limitation that the polymer is polyacrylamide. Since the approved product contains a polyacrylamide polymer, claim 14 also reads on a method of using the approved product.

Thus, product claims 1-3 and 5 and method claims 7-14 read directly on the approved product and a method of using such product, respectively.

X. Information Pursuant to 35 USC 156(g)

The information required by 37 CFR 1.740(a)(10)(v) is set forth below.

The effective date of the investigational device exemption (IDE) is October 13, 1986.[1] The IDE number is G860178. The first clinical study of "ORCOLON", U.S. Clinical Study I under IDE G860178, began on January 7, 1987.

A first application under § 515 of the Act for premarket approval, PMA application no. P870044, was initially filed on July 29, 1987. A second application for premarket approval (PMA application no. P900010) was filed February 13, 1990. The second application, P900010, was approved by the Food and Drug Administration (FDA) on March 29, 1991.

[1]An Investigational Device Exemption was granted for the medical device under the authority of § 520 of the Federal Food, Drug, and Cosmetic Act. June 25, 1938, c. 675, § 520 as added May 28, 1976, Pub.L. 94-295, § 2, 90 Stat. 565.

XI. Activities During Regulatory Review Period

Significant activities undertaken during the applicable regulatory review period with respect to the approved product and the dates applicable to such activities are described below.

Activities toward regulatory approval were initiated October 13, 1986, when an application for an IDE for "ORCOLON" was submitted by marketing applicant (Optical Radiation Corporation). A letter was received by marketing applicant on or about November 7, 1986, regarding discrepancies noted by the FDA. On December 1, 1986, marketing applicant submitted a response to deficiencies noted by the FDA. On December 10, 1986, marketing applicant filed a response to deficiencies noted in a telephone discussion with the FDA on December 8, 1986.

The first clinical study of "ORCOLON", U.S. Clinical Study I under IDE G860178, began January 7, 1987 and concluded in July of 1987. On January 26, 1987, marketing applicant responded to the FDA's deficiency letter of December 31, 1986. On March 18, 1987, a submission of information to the FDA was made on behalf of marketing applicant by American Cynamid Co. On April 20, 1987, marketing applicant submitted IRC approvals. On June 4, 1987, marketing applicant provided information requested in FDA letters dated February 27, 1987 and April 24, 1987.

On July 29, 1987, marketing applicant filed PMA application no. 870044 for "ORCOLON". Additional data and clarification of chemistry information were submitted on September 28, 1987. On

October 23, 1987, marketing applicant filed a PMA supplemental application responding to the FDA's deficiency letter dated October 13, 1987; also, marketing applicant filed an amendment on October 23, 1987, to correct information contained in the PMA supplemental application filed on the same date. A telephone call to the FDA was made by marketing applicant on November 19, 1987, inquiring into the status of the PMA application. Marketing applicant requested FDA export approval to Canada on December 7, 1987. Marketing applicant filed an Amendment on December 14, 1987.

On March 22, 1988, marketing applicant provided the FDA with a revised report, entitled "Sensitivity of Human Retinal Pigmented Epithelial (RPE) Cells to Acrylamide and Other Impurities", and provided a revised Section 3 of the PMA application (i.e., Summary of Data and Information). On March 28, 1988, marketing applicant filed an amendment changing the carboxylate units in response to the FDA's request of March 25, 1988. On April 7, 1988, fifteen copies of the revised PMA application were sent to the FDA in response to their request of March 25, 1988. Suspension of regulatory review of the "ORCOLON" PMA application was requested by marketing applicant on April 11, 1988. On May 12, 1988, marketing applicant filed an amendment changing the ammonia and lithium specifications and responding to FDA statements. Another amendment responding to an FDA letter dated May 10, 1988, was filed May 18, 1988. On May 20, 1988, an amendment was filed regarding the polyacrylamide. Then, on June 15, 1988, marketing applicant

submitted a response to the FDA's letter of the same date. On June 17, 1988, marketing applicant submitted a formal request to suspend PMA no. P870044.

On July 7, 1988, marketing applicant requested review of a draft protocol for a second U.S. study. On July 13, 1988, marketing applicant discussed with the FDA the proposed protocol for the study. On September 1, 1988, marketing applicant and the FDA discussed technical aspects of proposed testing regarding cytotoxicity, intraocular toxicity and basic toxicity profile. On September 28, 1988, marketing applicant filed an IDE supplement requesting FDA approval to conduct the second U.S. study. The request was disapproved by the FDA's letter of November 2, 1988, requesting additional product information, revision of data collection forms, drafts of package insert and labels, and information regarding the study design. On November 3, 1988, the FDA informed marketing applicant that the IDE supplement had been disapproved because of clinical and chemistry concerns. Marketing applicant discussed with the FDA matters pertaining to deficiencies on November 17, 1988. On November 25, 1988, the FDA informed marketing applicant that the target date for FDA response is December 10, 1988. On December 7, 1988, a response to the FDA letter dated November 2, 1988, was filed; a supplemental response correcting typographical errors in the December 7 response was submitted on December 23, 1988.

On January 13, 1989, marketing applicant provided the FDA with results of the intraocular irritation test. On January 19, 1989, marketing applicant submitted a response to the FDA's letter of January 6, 1989. On January 26, 1989, the FDA telephoned in response to marketing applicant's telephone messages of January 24 and 25, 1989. Marketing applicant received a disapproval letter dated February 21, 1989, from the FDA regarding the submission of January 19, 1989. On March 21, 1989, marketing applicant submitted results from a guinea pig maximization test. Marketing applicant received conditional approval to begin the study in the FDA's letter of April 21, 1989, which also requested modification of the study.

On May 2, 1989, marketing applicant telephoned the FDA and requested clarification of the FDA's request of April 21, 1989; details of the study were discussed. On May 8, 1989, difficulties with the study were discussed. On June 5, 1989, marketing applicant submitted a response to the FDA's conditional approval letter dated April 21, 1989. On June 19, 1989, marketing applicant provided the FDA with requested information regarding institutions involved with the study.

On July 13, 1989, marketing applicant requested approval for one year sterilization expiration dating and telephoned the FDA with questions regarding the study. By a letter dated July 14, 1989, the FDA approved continued study pursuant to marketing applicant's response filed June 5, 1989.

In a letter dated August 18, 1989, the FDA gave conditional approval for one lot in response to marketing applicant's request of July 13, 1989. On August 23, 1989, marketing applicant requested FDA approval of proposed modifications of the investigation. On August 30, 1989, marketing applicant responded to the FDA's letter of August 18, 1989, requesting molecular weight retest and data from an additional lot.

On September 22, 1989, marketing applicant received FDA conditional approval in response to their request of July 13, 1989. The FDA issued a letter dated September 29, 1989 requiring data on two lots of "ORCOLON" to validate sterility. On October 27, 1989, marketing applicant responded to the FDA's letter of September 22, 1989, for which approval was received by a letter from the FDA dated November 30, 1989. On December 11, 1989, marketing applicant submitted a revised protocol for sterility shelf-life study.

On January 12, 1990, the FDA issued a letter granting conditional approval in response to marketing applicant's submission of December 11, 1989, and set the time in which to submit data on the second lot. Marketing applicant's annual progress report was submitted February 5, 1990.

PMA application no. P900010 was filed on February 13, 1990. On February 13, 1990, marketing applicant also submitted shelf-life data for two lots and requested approval of one year sterility dating.

In response to the request of February 13, 1990, the FDA issued a disapproval letter dated March 15, 1990, requesting certain information. On March 22, 1990, marketing applicant telephoned the FDA; the FDA indicated that review of the second PMA application had not yet begun. On March 29, 1990, the FDA telephoned marketing applicant and requested copies of illegible pages, a diagram of a loaded sterilizer, lab reports for the sterilization cycle and validation of the half-cycle.

An acknowledgment letter from the FDA was received on April 12, 1990. On April 13, 1990, the FDA notified marketing applicant that a letter stating that the PMA is fileable is awaiting signature. On April 16, 1990, marketing applicant advised the FDA reviewer that phaco/nonphaco data were available. The FDA notified marketing applicant on April 27, 1990, that it had been requested to go to panel in June, which was followed by a call on May 4, 1990, notifying marketing applicant that the application would probably go to panel in June.

On May 11, 1990, marketing applicant filed an amendment providing information requested by the FDA on March 29 and May 1, 1990, including legible copies of illegible application papers, a diagram of a loaded sterilizer, lab reports for sterilization and validation of half-cycle, a risk analysis, a picture of the product and a report of lost-to-followup patients. Approval of one year sterility shelf life was granted by the FDA in a letter dated May 16, 1990. On May 25, 1990, marketing applicant provided the FDA

with information regarding sterilization validation and shelf-life study.

Bacteriostasis and fungistasis test results were filed June 1, 1990; on the same date, the FDA notified marketing applicant of a radio-labelling question and marketing applicant agreed to meet before the panel. The FDA notified marketing applicant on June 4, 1990, that the FDA panel meeting would be on June 14, 1990. On June 8, 1990, marketing applicant met with the FDA, and discussed metabolism and elimination of the product in rabbits. An amendment was submitted June 11, 1990, providing a transcript of a presentation made in April of 1989. Also on June 11, 1990, marketing applicant telephoned the FDA to ask if there were any additional questions or concerns regarding the PMA application. On June 14, 1990, panel approval was received.

On July 16, 1990, marketing applicant inquired into the review process after panel approval. On August 9, 1990, the FDA notified marketing applicant that review was still ongoing. On August 29 and 30, 1990, marketing applicant telephoned the FDA to inquire as to whether a response could be submitted prior to issuance of an official letter; the FDA advised against submitting a response at that time.

On September 21, 1990, marketing applicant telephoned the FDA, inquiring into the status of the application. Another amendment was filed October 11, 1990, providing information and data pertaining to a rabbit radio-label study in response to the FDA's

deficiency letter dated September 25, 1990; marketing also informed the FDA that a response was being sent on October 11, 1990. The FDA telephoned on October 16 and October 25, 1990, to inform marketing applicant of the progress of the review and note that the FDA had written to consult a veterinarian.

On November 29, 1990, the FDA informed marketing applicant that the veterinary consultant's comments had not yet been received. Marketing applicant telephoned the FDA on November 30, 1990; in response to marketing applicant's inquiry, the FDA stated that the application was still under review. On December 3, 1990, marketing applicant telephoned the FDA for clarification of the FDA's concerns about polyacrylamide. The FDA notified marketing applicant of the status of the review on December 17, 1990.

On January 2 and 10, 1991, marketing applicant called the FDA and inquired into the stage of the review process. On January 11, 1991, the FDA agreed to meet with marketing applicant to discuss PMA application supplements. On January 23 and 24, 1991, marketing applicant called the FDA to request confirmation of premarket approval and discuss picking up the approval letter via courier.

On February 1 and 8, 1991, marketing applicant spoke with the FDA regarding the status of the approval letter. On February 4, 1991, the FDA returned marketing applicant's telephone call of January 25, 1991, and noted that the letter and summary of safety and effectiveness were awaiting correction. On February 19, and March 5 and 6, 1991, the FDA and marketing applicant telephonically

discussed matters relating to the safety, effectiveness and labelling of the product.

Marketing applicant submitted an annual progress report on March 1, 1991. On March 11, 1991, marketing applicant requested a meeting with the FDA; the FDA requested marketing applicant to contact them on March 12 or 13, 1991. Accordingly, on March 13, 1991, marketing applicant again requested a meeting, but the FDA indicated that there was no need for a meeting.

On March 14, 20, 26, 27 and 28, 1991, telephone interviews between marketing applicant and the FDA were conducted to further discuss matters pertaining to the safety, effectiveness and labelling of the product; marketing applicant sent two amendments on March 27 and 28, 1991, to the FDA accepting the changes discussed in the telephone conversations. Finally, the FDA granted premarket approval of "ORCOLON" on March 29, 1991.

XII. Eligibility Of Patent For Extension

In the opinion of Applicant, the above-captioned reissue patent is eligible for an extension of the term to expire March 29, 2005. The length of the claimed extension was determined by Applicant pursuant to 37 CFR 1.777 as described below.

Length of Regulatory Review Period (Rule 777(c)):

The regulatory review period was first determined to be 1628 days by adding together the length of the (c)(1) and (c)(2) periods.

Period Pursuant to Paragraph (c)(1):

The period defined at 37 CFR 1.777(c)(1) began October 13, 1986 (the effective date of the IDE) and ended July 29, 1987 (the date the first PMA application was initially filed). Thus, the total (c)(1) period is 289 days.

Period Pursuant to Paragraph (c)(2):

The period defined at 37 CFR 1.777(c)(2) began July 29, 1987 and ended March 29, 1991 (the PMA approval date). The (c)(2) period is thus 1339 days.

Term of the Patent as Extended (Rule 777(d)):

The term of the patent as extended was then calculated to expire on March 29, 2005, pursuant to 37 CFR 1.777(d).

(d)(1) Period (Days Subtracted from Regulatory Review Period):

(i) No days in the periods of paragraphs (c)(1) and (c)(2) above were on or before September 10, 1985, the issue date of the original patent. Since the reissued product claims 1-6 are effectively the same as the product claims in the original patent

except for minor matters of form not affecting the scope of the original claims, the September 10, 1985 issue date of the original patent is the effective issue date of the reissued product claims.

Although the process claims 7-17 in the reissue patent are not present in the original patent, in Applicant's opinion the issue date of the original patent is also the effective issue date of the process claims in the reissue patent for the purpose of determining the number of days pursuant to 37 CFR 1.777(d)(1)(i). The date of issue of the reissue patent is effective for determining intervening rights according to 35 USC 252, second paragraph. Thus, § 252 governs how such intervening rights are determined, and the use of the original issue date to calculate the period at issue will not prejudice such rights. Accordingly, it is appropriate to use September 10, 1985 as the issue date of the process claims of the reissue patent to determine the number of days pursuant to subparagraph (d)(1)(i) to determine the length of the patent term extension with respect to parties not entitled to such intervening rights.

In view of the foregoing, since no days in the periods of paragraphs (c)(1) and (c)(2) were on or before September 10, 1985, the number of days to be subtracted from the regulatory review period is zero.

(ii) In Applicant's opinion, marketing applicant acted with due diligence as defined at 35 USC 156(d)(3) during the above-calculated periods of paragraphs (c)(1) and (c)(2). Accordingly, zero days are subtracted from the regulatory review period.

(iii) Thus, after subtraction of no days as in subparagraphs (i) and (ii) immediately above, the number of days remaining in the (c)(1) period is 289 days. One-half of 289 days is 144.5 days. From the total of the (c)(1) and (c)(2) periods, a period of 1484 days remains after subtracting 144 days (ignoring the half day) from 1628 days in accordance with Rule 777(d)(1)(iii).

Thus, the period determined according to paragraph (d)(1) is 1484 days.

(d)(2) Date:

The number of days determined in paragraph (d)(1), 1484 days, added to the original term of the patent, 17 years, results in an extended patent expiration date of November 15, 2006.

(d)(3) Date:

Fourteen years added to the March 29, 1991 date of approval under the Federal Food, Drug and Cosmetic Act, yields an extended patent expiration date of March 29, 2005.

(d)(4) Date:

Comparing the extended terms determined according to paragraphs (d)(3) and (d)(4), the earlier date is March 29, 2005.

(d)(5) Date:

The original patent was issued after September 24, 1984. Thus, a date pursuant to paragraph (d)(5) is found by:

(i) adding 5 years to the original expiration date of the patent, resulting in a date of September 10, 2007; and

(ii) selecting March 29, 2005 as the earlier of the dates according to paragraphs (d)(5)(i) and (d)(4).

Therefore, Applicant respectfully requests an extension of 888 days, to March 29, 2005.

XIII. Acknowledgment of Duty to Disclose

Applicant hereby acknowledges a duty to disclose to the Commissioner of Patents and Trademarks and the Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension sought pursuant to 37 CFR 1.765.

XIV. Application Fee

Applicant submits herewith a check for $600.00 in payment of the fee set forth at 37 CFR 1.20(n). In the event the enclosed payment is for any reason insufficient, Applicant hereby authorizes payment of any fees required for this application from our Deposit Account 23-0783.

XV. Correspondence Address

Send correspondence and direct inquiries to:

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FIDELMAN & WOLFFE
P.O. Box 18218
Washington, DC 20036-8218

Telephone No.: (202) 833-8801.

XVI. Duplicate of Application and Certification

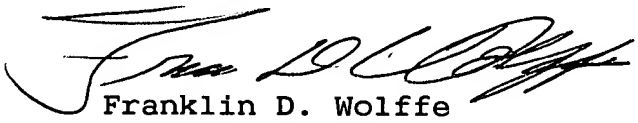
Applicant encloses herewith a copy of the present application papers, and certifies that said copy is a duplicate of the application papers.

XVII. Declaration

A declaration pursuant to 37 CFR 1.740(b) is attached hereto. In conjunction with the declaration, also enclosed is a power of attorney signed by Seymour F. Trager and a facsimile of a power of attorney signed by Victoria S. Chylinski granting the undersigned general authority to act on behalf of the patent owner in patent matters. The original power of attorney executed by Victoria S. Chylinski will be filed upon receipt by the undersigned.

In view of the foregoing, an extension of the term of the above-captioned reissue patent is requested.

Respectfully submitted,



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Date: May 28, 1991
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Patentee: Trager et al.

Title: INJECTIONABLE VISCOELASTIC OPHTHALMIC GEL

DECLARATION UNDER 37 CFR 1.740(a)(17)

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

Sir:

I am a patent attorney or agent for the owner of record of the above-captioned U.S. Patent No. Re. 32,969 for which a patent term extension is sought, authorized to practice before the Patent and Trademark Office, and have general authority from said owner to act on behalf of said owner in patent matters including the execution of the APPLICATION FOR EXTENSION OF PATENT TERM attached hereto.

I have reviewed and understand the contents of the attached APPLICATION FOR EXTENSION OF PATENT TERM being submitted pursuant to 37 CFR 1.740.

I believe that said patent is subject to extension pursuant to 37 CFR 1.710.

I believe that an extension of the length claimed is justified under 35 USC 156 and the applicable regulations.

I believe that the patent for which the extension is being sought meets the conditions for extension of the term of a patent as set forth in 37 CFR 1.720.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code.

Franklin D. Wolffe
Reg. No. 19,724

5/20/91
Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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U.S. Patent No.: Re. 32,969

Reissued Date of Patent: June 27, 1989

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INJECTIONABLE VISCOELASTIC OPHTHALMIC GEL

POWER OF ATTORNEY

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

Sir:

As a named inventor and patent owner of record of U.S. Patent Re. 32,969, issued June 27, 1989, a reissue of U.S. Patent No. 4,540,568, issued September 10, 1985, of which I am also a named inventor and patent owner of record, I hereby appoint the following attorneys to prosecute the above-captioned application for extension of patent term, including execution of the application declaration, with general authority to act on my behalf in patent matters and to transact all business in connection therewith in the Patent and Trademark Office:

Franklin D. Wolffe, Reg. No. 19,724
Douglas P. Mueller, Reg. No. 30,300
Harold C. Wegner, Reg. No. 25,258
Herbert I. Cantor, Reg. No. 24,392
William E. Player, Reg. No. 31,409
Linda S. Evans, Reg. No. 33,873

Victoria S. Chylinski

Victoria S. Chylinski

26th May 1991.
Date